



Update and Interim Guidance on Infection Prevention and Control for 2019 Novel Coronavirus (2019-nCoV)

Date: January 30, 2020

Public Health Message Type: ☐ Alert ☐ Advisory ☒ Update ☐ Information

Intended Audience: ☐ All public health partners ☒ Healthcare providers ☒ Infection preventionists
☒ Local health departments ☐ Schools/child care centers ☐ ACOs
☐ Animal health professionals ☐ Other:

Key Points or Updates:

- (1) A novel coronavirus (2019-nCoV) has been identified as the causative agent in the recent respiratory illness outbreak occurring in Wuhan City, Hubei Province, China.
- (2) The most recent international case counts can be found [here](https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports/):
<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports/>
- (3) The most recent United States case counts and situation summary can be found [here](https://www.cdc.gov/coronavirus/2019-ncov/cases-in-us.html):
<https://www.cdc.gov/coronavirus/2019-ncov/cases-in-us.html>
- (4) The risk to the general public in the U.S. remains low
- (5) Many persons who have symptoms or travel risk are seeking care in outpatient and acute care settings.
- (6) CDC has issued the document, [Interim Infection Prevention and Control Recommendations for Patients with Known or Patients Under Investigation for 2019 Novel Coronavirus \(2019-nCoV\) in a Healthcare Setting \(Attachment A\)](#), in an effort to prevent the spread of infection during healthcare delivery. This guidance is not intended for non-healthcare settings (e.g., schools) OR to persons outside of healthcare settings.
- (7) This guidance is based on the currently limited information available about 2019-nCoV related to disease severity, transmission efficiency, and shedding duration. This cautious approach will be refined and updated as more information becomes available and as response needs change in the United States.
- (8) The CDC has also provided two checklists: [Hospital Preparedness Checklist \(Attachment B\)](#) and [Healthcare Providers Preparedness Checklist \(Attachment C\)](#). These are available to aid healthcare facilities in preparing to receive and evaluate potential cases or persons under investigation (PUIs) for 2019-nCoV.

Action Items:

- (1) Infection preventionists, hospital epidemiologists and healthcare providers should carefully review information contained in the [Interim Infection Prevention and Control Recommendations for Patients with Known or Patients Under Investigation for 2019 Novel Coronavirus \(2019-nCoV\) in a Healthcare Setting](#) regarding infection control and prevention measures to minimize possible exposure to, and transmission of 2019-nCoV.

(2) Providers should continue to report individuals meeting the following criteria:

Clinical Features	&	Epidemiologic Risk
Fever or signs/symptoms of lower respiratory illness (e.g. cough or shortness of breath)	AND	Any person, including health care workers, who has had close contact with a laboratory-confirmed 2019-nCoV patient within 14 days of symptom onset
Fever and signs/symptoms of a lower respiratory illness (e.g., cough or shortness of breath)	AND	A history of travel from Hubei Province , China within 14 days of symptom onset
Fever and signs/symptoms of a lower respiratory illness (e.g., cough or shortness of breath) requiring hospitalization ⁴	AND	A history of travel from mainland China within 14 days of symptom onset

The criteria are intended to serve as guidance for evaluation. Patients should be evaluated and discussed with public health departments on a case-by-case basis if their clinical presentation or exposure history is equivocal (e.g., uncertain travel or exposure).

- (3) Patients meeting the above criteria should be reported **IMMEDIATELY** to local departments of health, and strict infection control guidelines should be implemented to avoid potential transmission until the patient can be further evaluated and/or ruled out for 2019-nCoV infection.
- (4) Environmental infection control guidance includes the use of products with an EPA-approved emerging viral pathogen claim.
- These products can be identified by the following claim:
“[Product name] has demonstrated effectiveness against viruses similar to 2019-nCoV on hard non-porous surfaces. Therefore, this product can be used against 2019-nCoV when used in accordance with the directions for use against [name of supporting virus] on hard, non-porous surfaces.”
 - Additional guidance on identification of these products is available from the EPA in the [Emerging Viral Pathogen Guidance](#) (**Attachment D**)

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References and Resources:

- **Interim Infection Prevention and Control Recommendations for Patients with Known or Patients Under Investigation for 2019 Novel Coronavirus (2019-nCoV) in a Healthcare Setting**
 - <https://www.cdc.gov/coronavirus/2019-nCoV/hcp/infection-control.html>
- **Hospital Preparedness Checklist**
 - <https://www.cdc.gov/coronavirus/2019-ncov/hcp/hcp-hospital-checklist.html>
- **Healthcare Providers Preparedness Checklist**
 - <https://www.cdc.gov/coronavirus/2019-ncov/hcp/hcp-personnel-checklist.html>
- **CDC Novel Coronavirus**
 - <https://www.cdc.gov/coronavirus/2019-nCoV/summary.html>
- **EPA guidance on Emerging Viral Pathogens**
 - https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf



2019 Novel Coronavirus

Interim Infection Prevention and Control Recommendations for Patients with Known or Patients Under Investigation for 2019 Novel Coronavirus (2019-nCoV) in a Healthcare Setting

Background

Infection control procedures including administrative rules and engineering controls, environmental hygiene, correct work practices, and appropriate use of personal protective equipment (PPE) are all necessary to prevent infections from spreading during healthcare delivery. Prompt detection and effective triage and isolation of potentially infectious patients are essential to prevent unnecessary exposures among patients, healthcare personnel, and visitors at the facility. All healthcare facilities must ensure that their personnel are correctly trained and capable of implementing infection control procedures; individual healthcare personnel should ensure they understand and can adhere to infection control requirements.

This guidance is based on the currently limited information available about 2019-nCoV related to disease severity, transmission efficiency, and shedding duration. This cautious approach will be refined and updated as more information becomes available and as response needs change in the United States. This guidance is applicable to all U.S. healthcare settings. **This guidance is not intended for non-healthcare settings (e.g., schools) OR to persons outside of healthcare settings.** For recommendations regarding clinical management, air or ground medical transport, or laboratory settings, refer to the main CDC [2019-nCoV website](https://www.cdc.gov/2019-ncov/).

Definition of Healthcare Personnel (HCP) – For the purposes of this guidance, HCP refers to all persons, paid and unpaid, working in healthcare settings engaged in patient care activities, including: patient assessment for triage, entering examination rooms or patient rooms to provide care or clean and disinfect the environment, obtaining clinical specimens, handling soiled medical supplies or equipment, and coming in contact with potentially contaminated environmental surfaces.

Recommendations

1. Minimize Chance for Exposures

Ensure facility policies and practices are in place to minimize exposures to respiratory pathogens including 2019-nCoV. Measures should be implemented before patient arrival, upon arrival, and throughout the duration of the affected patient's presence in the healthcare setting.

- **Before Arrival**

- When scheduling appointments, instruct patients and persons who accompany them to call ahead or inform HCP upon arrival if they have symptoms of any respiratory infection (e.g., cough, runny nose, fever¹) and to take appropriate preventive actions (e.g., wear a facemask upon entry to contain cough, follow triage procedures).
- If a patient is arriving via transport by emergency medical services (EMS), the driver should contact the receiving emergency department (ED) or healthcare facility and follow previously agreed upon local or regional transport protocols. This will allow the healthcare facility to prepare for receipt of the patient.

- **Upon Arrival and During the Visit**

- Take steps to ensure all persons with symptoms of suspected 2019-nCoV or other respiratory infection (e.g., fever, cough) adhere to respiratory hygiene and cough etiquette, hand hygiene, and triage procedures throughout the duration of the visit. Consider posting visual alerts (e.g., signs, posters) at the entrance and in strategic places (e.g.,

waiting areas, elevators, cafeterias) to provide patients and HCP with instructions (in appropriate languages) about hand hygiene, respiratory hygiene, and cough etiquette. Instructions should include how to use facemasks (See definition of facemask in Appendix) or tissues to cover nose and mouth when coughing or sneezing, to dispose of tissues and contaminated items in waste receptacles, and how and when to perform hand hygiene.

- Ensure that patients with symptoms of suspected 2019-nCoV or other respiratory infection (e.g., fever, cough) are not allowed to wait among other patients seeking care. Identify a separate, well-ventilated space that allows waiting patients to be separated by 6 or more feet, with easy access to respiratory hygiene supplies. In some settings, patients might opt to wait in a personal vehicle or outside the healthcare facility where they can be contacted by mobile phone when it is their turn to be evaluated.
- Ensure rapid triage and isolation of patients with symptoms of suspected 2019-nCoV or other respiratory infection (e.g., fever, cough):
 - Identify patients at risk for having 2019-nCoV infection before or immediately upon arrival to the healthcare facility.
- Implement triage procedures to detect [patients under investigation \(PUI\) for 2019-nCoV](#) during or before patient triage or registration (e.g., at the time of patient check-in) and ensure that all patients are asked about the presence of symptoms of a respiratory infection and history of travel to areas experiencing transmission of 2019-nCoV or contact with possible 2019-nCoV patients.
 - Implement respiratory hygiene and cough etiquette (i.e., placing a facemask over the patient's nose and mouth if that has not already been done) and isolate the PUI for 2019-nCoV in an Airborne Infection Isolation Room (AIIR), if available. See recommendations for "Patient Placement" below. Additional guidance for evaluating patients in U.S. for 2019-nCoV infection can be found on the CDC [2019-nCoV website](#).
 - Inform infection prevention and control services, local and state public health authorities, and other healthcare facility staff as appropriate about the presence of a patient under investigation for 2019-nCoV.
- Provide supplies for respiratory hygiene and cough etiquette, including 60%-95% alcohol-based hand rub (ABHR), tissues, no touch receptacles for disposal, and facemasks at healthcare facility entrances, waiting rooms, patient check-ins, etc.

2. Adherence to Standard, Contact and Airborne Precautions, Including the Use of Eye Protection

Standard Precautions assume that every person is potentially infected or colonized with a pathogen that could be transmitted in the healthcare setting. Elements of Standard Precautions that apply to patients with respiratory infections, including those caused by 2019-nCoV, are summarized below. Attention should be paid to training and proper donning (putting on), doffing (taking off), and disposal of any PPE. This document does not emphasize all aspects of Standard Precautions (e.g., injection safety) that are required for all patient care; the full description is provided in the [Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings](#). All HCP (see section 3 for measures for non-HCP visitors) who enter the room of a patient with suspected or confirmed 2019-nCoV should adhere to Standard, Contact, and Airborne Precautions, including the following:

- **Patient Placement**
 - Place a patient with known or suspected 2019-nCoV (i.e., PUI) in an AIIR that has been constructed and maintained in accordance with current guidelines.
 - AIIRs are single patient rooms at negative pressure relative to the surrounding areas, and with a minimum of 6 air changes per hour (12 air changes per hour are recommended for new construction or renovation). Air from these rooms should be exhausted directly to the outside or be filtered through a high-efficiency particulate air (HEPA) filter before recirculation. Room doors should be kept closed except when entering or leaving the room, and entry and exit should be minimized. Facilities should monitor and document the proper negative-pressure function of these rooms.
 - If an AIIR is not available, the patient should be transferred as soon as is feasible to a facility where an AIIR is available or discharged to home (in consultation with state or local public health authorities) if deemed medically appropriate. Pending transfer, place a facemask on the patient and isolate him/her in an examination room with the door closed. The patient should not be placed in any room where room exhaust is recirculated within the building without HEPA filtration.
 - Once in an AIIR, the patient's facemask may be removed. Limit transport and movement of the patient outside of the AIIR to medically essential purposes. When not in an AIIR (e.g., during transport or if an AIIR is not available)

the AHR to medically essential purposes. When not in an AHR (e.g., during transport or if an AHR is not available), patients should wear a facemask to contain secretions.

- Personnel entering the room should use PPE, including respiratory protection, as described below.
 - Only essential personnel should enter the AHR. Implement staffing policies to minimize the number of HCP who enter the room.
 - Facilities should consider caring for these patients with dedicated HCP to minimize risk of transmission and exposure to other patients and other HCP.
 - Facilities should keep a log of all persons who care for or enter the rooms or care area of these patients.
- Use dedicated or disposable noncritical patient-care equipment (e.g., blood pressure cuffs). If equipment will be used for more than one patient, clean and disinfect such equipment before use on another patient according to manufacturer's instructions.
 - HCP entering the AHR soon after a patient vacates the room should use respiratory protection. (See personal protective equipment section below) Standard practice for pathogens spread by the airborne route (e.g., measles, tuberculosis) is to restrict unprotected individuals, including HCP, from entering a vacated room until sufficient time has elapsed for enough air changes to remove potentially infectious particles (more information on [clearance rates under differing ventilation conditions](#) is available). We do not yet know how long 2019-nCoV remains infectious in the air. In the interim, it is reasonable to apply a similar time period before entering the room without respiratory protection as used for pathogens spread by the airborne route (e.g., measles, tuberculosis). In addition, the room should undergo appropriate cleaning and surface disinfection before it is returned to routine use.
- **Hand Hygiene**
 - HCP should perform hand hygiene using ABHR before and after all patient contact, contact with potentially infectious material, and before putting on and upon removal of PPE, including gloves. Hand hygiene in healthcare settings also can be performed by washing with soap and water for at least 20 seconds. If hands are visibly soiled, use soap and water before returning to ABHR.
 - Healthcare facilities should ensure that hand hygiene supplies are readily available to all personnel in every care location.
- **Personal Protective Equipment**

Employers should select appropriate PPE and provide it to HCP in accordance with [OSHA's PPE standards \(29 CFR 1910 Subpart I\)](#) [↗](#). HCP must receive training on and demonstrate an understanding of when to use PPE; what PPE is necessary; how to properly don, use, and doff PPE in a manner to prevent self-contamination; how to properly dispose of or disinfect and maintain PPE; and the limitations of PPE. Any reusable PPE must be properly cleaned, decontaminated, and maintained after and between uses. Facilities should have policies and procedures describing a recommended sequence for safely donning and doffing PPE:

 - **Gloves**
 - Perform hand hygiene, then put on clean, non-sterile gloves upon entry into the patient room or care area. Change gloves if they become torn or heavily contaminated.
 - Remove and discard gloves when leaving the patient room or care area, and immediately perform hand hygiene.
 - **Gowns**
 - Put on a clean disposable gown upon entry into the patient room or area. Change the gown if it becomes soiled. Remove and discard the gown before leaving the patient room or care area.
 - **Respiratory Protection**
 - Use respiratory protection (i.e., a respirator) that is at least as protective as a fit-tested NIOSH-certified disposable N95 filtering facepiece respirator before entry into the patient room or care area. See appendix for respirator definition.
 - Disposable respirators should be removed and discarded after exiting the patient's room or care area and closing the door. Perform hand hygiene after discarding the respirator.
 - If reusable respirators (e.g., powered air purifying respirator/PAPR) are used, they must be cleaned and disinfected according to manufacturer's reprocessing instructions prior to re-use.
 - Respirator use must be in the context of a complete respiratory protection program in accordance with Occupational Safety and Health Administration (OSHA) Respiratory Protection standard ([29 CFR 1910.134](#) [↗](#)). Staff should be medically cleared and fit-tested if using respirators with tight-fitting facepieces (e.g., a NIOSH-certified disposable N95) and trained in the proper use of respirators, safe removal and disposal, and medical contraindications to respirator use.

- **Eye Protection**
 - Put on eye protection (e.g., goggles, a disposable face shield that covers the front and sides of the face) upon entry to the patient room or care area. Remove eye protection before leaving the patient room or care area. Reusable eye protection (e.g., goggles) must be cleaned and disinfected according to manufacturer's reprocessing instructions prior to re-use. Disposable eye protection should be discarded after use.
- **Use Caution When Performing Aerosol-Generating Procedures**
 - Some procedures performed on 2019-nCoV patients could generate infectious aerosols. In particular, procedures that are likely to induce coughing; e.g., nasopharyngeal specimen collection, sputum induction, and open suctioning of airways should be performed cautiously and avoided if possible.
 - If performed, these procedures should take place in an AIIR, and personnel should use respiratory protection as described above. In addition:
 - Limit the number of HCP present during the procedure to only those essential for patient care and procedural support.
 - Clean and disinfect procedure room surfaces promptly as described in the section on environmental infection control below.
- **Duration of Isolation Precautions**
 - Until information is available regarding viral shedding after clinical improvement, discontinuation of isolation precautions should be determined on a case-by-case basis, in conjunction with local, state, and federal health authorities.
 - Factors that should be considered include: presence of symptoms related to 2019-nCoV, date symptoms resolved, other conditions that would require specific precautions (e.g., tuberculosis, *Clostridioides difficile*), other laboratory information reflecting clinical status, alternatives to inpatient isolation, such as the possibility of safe recovery at home.

3. Manage Visitor Access and Movement Within the Facility

- Establish procedures for monitoring, managing and training visitors.
- Restrict visitors from entering the room of known or suspected 2019-nCoV patients (i.e., PUI). Alternative mechanisms for patient and visitor interactions, such as video-call applications on cell phones or tablets should be explored. Facilities can consider exceptions based on end-of-life situations or when a visitor is essential for the patient's emotional well-being and care.
- Visitors to known or suspected 2019-nCoV (i.e., PUI) patients should be scheduled and controlled to allow for:
 - Screening visitors for symptoms of acute respiratory illness before entering the healthcare facility.
 - Facilities should evaluate risk to the health of the visitor (e.g., visitor might have underlying illness putting them at higher risk for 2019-nCoV) and ability to comply with precautions.
 - Facilities should provide instruction, before visitors enter patients' rooms, on hand hygiene, limiting surfaces touched, and use of PPE according to current facility policy while in the patient's room.
 - Facilities should maintain a record (e.g., log book) of all visitors who enter patient rooms.
 - Visitors should not be present during aerosol-generating procedures.
 - Visitors should be instructed to limit their movement within the facility.
 - Exposed visitors (e.g., contact with symptomatic 2019-nCoV patient prior to admission) should be advised to report any signs and symptoms of acute illness to their health care provider for a period of at least 14 days after the last known exposure to the sick patient.
- All visitors should follow respiratory hygiene and cough etiquette precautions while in the common areas of the facility.


4. Implement Engineering Controls

- Consider designing and installing engineering controls to reduce or eliminate exposures by shielding HCP and other patients from infected individuals. Examples of engineering controls include physical barriers or partitions to guide patients through triage areas, curtains between patients in shared areas, closed suctioning systems for airway suctioning for intubated patients, as well as appropriate air-handling systems (with appropriate directionality, filtration, exchange rate, etc.) that are installed and properly maintained.


5. Monitor and Manage Ill and Exposed Healthcare Personnel

- Movement and monitoring decisions for HCP with exposure to 2019-nCoV should be made in consultation with public health authorities.
- Facilities and organizations providing healthcare should implement [sick leave policies](#) for HCP that are non-punitive, flexible, and consistent with public health guidance.

6. Train and Educate Healthcare Personnel

- Provide HCP with job- or task-specific education and training on preventing transmission of infectious agents, including refresher training.
- HCP must be medically cleared, trained, and fit tested for respiratory protection device use (e.g., N95 filtering facepiece respirators), or medically cleared and trained in the use of an alternative respiratory protection device (e.g., Powered Air-Purifying Respirator, PAPR) whenever respirators are required. OSHA has a number of [respiratory training videos](#) .
- Ensure that HCP are educated, trained, and have practiced the appropriate use of PPE prior to caring for a patient, including attention to correct use of PPE and prevention of contamination of clothing, skin, and environment during the process of removing such equipment.

7. Implement Environmental Infection Control

- Dedicated medical equipment should be used for patient care.
- All non-dedicated, non-disposable medical equipment used for patient care should be cleaned and disinfected according to manufacturer's instructions and facility policies.
- Ensure that environmental cleaning and disinfection procedures are followed consistently and correctly.
- Routine cleaning and disinfection procedures (e.g., using cleaners and water to pre-clean surfaces prior to applying an EPA-registered, hospital-grade disinfectant to frequently touched surfaces or objects for appropriate contact times as indicated on the product's label) are appropriate for 2019-nCoV in healthcare settings, including those patient-care areas in which aerosol-generating procedures are performed. Products with EPA-approved emerging viral pathogens claims are recommended for use against 2019-nCoV. These products can be identified by the following claim:
 - "[Product name] has demonstrated effectiveness against viruses similar to 2019-nCoV on hard non-porous surfaces. Therefore, this product can be used against 2019-nCoV when used in accordance with the directions for use against [name of supporting virus] on hard, non-porous surfaces."
 - This claim or a similar claim, will be made only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). Specific claims for "2019-nCoV" will not appear on the product or master label.
 - Additional information about EPA-approved emerging viral pathogens claims can be found here: <https://www.epa.gov/pesticide-registration/guidance-registrants-process-making-claims-against-emerging-viral-pathogens> .
 - If there are no available EPA-registered products that have an approved emerging viral pathogen claim for 2019-nCoV, products with label claims against human coronaviruses should be used according to label instructions.
- Management of laundry, food service utensils, and medical waste should also be performed in accordance with routine procedures.
- Detailed information on environmental infection control in healthcare settings can be found in CDC's [Guidelines for Environmental Infection Control in Health-Care Facilities](#) and [Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings](#) [section IV.F. Care of the environment].

8. Establish Reporting within Healthcare Facilities and to Public Health Authorities

- Implement mechanisms and policies that promptly alert key facility staff including infection control, healthcare epidemiology, facility leadership, occupational health, clinical laboratory, and frontline staff about known or suspected 2019-nCoV patients (i.e., PUI).
- Communicate and collaborate with public health authorities.

- Promptly notify state or local public health authorities of known or suspected 2019-nCoV patients (i.e., PUI). Facilities should designate specific persons within the healthcare facility who are responsible for communication with public health officials and dissemination of information to HCP.

Appendix: Additional Information about Respirators and Facemasks

Information about Respirators:

- A respirator is a personal protective device that is worn on the face, covers at least the nose and mouth, and is used to reduce the wearer's risk of inhaling hazardous airborne particles (including dust particles and infectious agents), gases, or vapors. Respirators are certified by the CDC/NIOSH, including those intended for use in healthcare.
- Respirator use must be in the context of a complete respiratory protection program in accordance with OSHA Respiratory Protection standard ([29 CFR 1910.134](https://www.cdc.gov/niosh/publications/OSHA-3095.pdf) [↗](#)). HCP should be medically cleared and fit-tested if using respirators with tight-fitting facepieces (e.g., a NIOSH-approved N95 respirator) and trained in the proper use of respirators, safe removal and disposal, and medical contraindications to respirator use.
- [NIOSH information about respirators](#)
- [OSHA Respiratory Protection eTool](#) [↗](#)

Filtering Facepiece Respirators (FFR) including N95 Respirators

- A commonly used respirator is a filtering facepiece respirator (commonly referred to as an N95). Filtering facepiece respirators are disposable half facepiece respirators that filter out particles.
- To work properly, FFRs must be worn throughout the period of exposure and be specially fitted for each person who wears one (this is called "fit-testing" and is usually done in a workplace where respirators are used).
- Three key factors for an N95 respirator to be effective:
(<https://www.cdc.gov/niosh/npptl/pdfs/KeyFactorsRequiredResp01042018-508.pdf> [↗](#))
- FFR users should also perform a user seal check to ensure proper fit each time an FFR is used.
- For more information on how to perform a user seal check: <https://www.cdc.gov/niosh/docs/2018-130/pdfs/2018-130.pdf?id=10.26616/NIOSH-PUB2018130> [↗](#)

A list of NIOSH-approved N95 respirators is located here:

https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/n95list1.html

Powered Air-Purifying Respirators (PAPRs)

- Powered air-purifying respirators (PAPRs) have a battery-powered blower that pulls air through attached filters, canisters, or cartridges. They provide protection against gases, vapors, or particles, when equipped with the appropriate cartridge, canister, or filter.
- Loose-fitting PAPRs do not require fit testing and can be used with facial hair.
- A list of NIOSH-approved PAPRs is located on the NIOSH Certified Equipment List:
<https://www.cdc.gov/niosh/npptl/topics/respirators/cel/>

Information about Facemasks:

- If worn properly, a facemask helps block respiratory secretions produced by the wearer from contaminating other persons and surfaces (often called source control).
- Facemasks are cleared by the U.S. Food and Drug Administration (FDA) for use as medical devices. Facemasks should be used once and then thrown away in the trash.

Interim Guidance for Implementing Home Care of People Not Requiring Hospitalization for 2019 Novel Coronavirus (2019-nCoV)

CDC has developed interim guidance for staff at local and state health departments, infection prevention and control professionals, healthcare providers, and healthcare workers who are coordinating the home care and isolation of people who are confirmed to have, or being evaluated for 2019 novel coronavirus (2019-nCoV) infection (see Criteria to Guide Evaluation of Patients Under Investigation (PUI) for 2019-nCoV).

[Interim Guidance for Implementing Home Care of People Not Requiring Hospitalization for 2019 Novel Coronavirus \(2019-nCoV\)](#)

Important Links

- [Respirator Trusted-Source Information](#)
- [Respirator Fact Sheet](#)

Footnote

1. Fever may not be present in some patients, such as those who are very young, elderly, immunosuppressed, or taking certain medications. Clinical judgement should be used to guide testing of patients in such situations.

Page last reviewed: January 28, 2020



2019 Novel Coronavirus (2019-nCoV) Hospital Preparedness Checklist

All U.S. hospitals need to be prepared for patients with suspected or confirmed 2019 novel coronavirus (2019-nCoV). All hospitals should be equipped and ready to:

- prevent spread of 2019-nCoV
- identify and isolate patients with 2019-nCoV and inform key facility staff and public health authorities
- care for a limited number of patients with known or suspected 2019-nCoV as part of routine operations
- potentially care for a larger number of patients in the context of escalating transmission
- outline plans for internal and external communication
- monitor and manage healthcare personnel with potential for exposure to 2019-nCoV
- manage the impact on patients, the facility, and healthcare personnel

The following checklist highlights some key areas for hospitals to review in preparation for 2019-nCoV. The checklist format is not intended to set forth mandatory requirements or establish national standards.

- Ensure facility infection prevention and control policies are consistent with the Centers for Disease Control and Prevention's 2019-nCoV guidance (<https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html>).
- Review procedures for rapidly identifying and isolating suspected 2019-nCoV patients,
- Assure ability to implement triage activities based on public health guidance including at the facility and using remote (i.e., phone, internet-based) methods where appropriate to minimize demand on the health care system.
- Ensure that negative-pressure airborne infection isolation rooms are available and functioning correctly and are appropriately monitored for airflow and exhaust handling.
- Assess availability of personal protective equipment (PPE) and other infection prevention and control supplies (e.g., hand hygiene supplies) that would be used for both healthcare personnel (HCP) protection and source control for infected patients (e.g., facemask on the patient).
- Have contingency plans if the demand for PPE or other supplies exceeds supply.
- Review plans for implementation of surge capacity procedures and crisis standards of care.
- Review procedures for laboratory submission of specimens for 2019-nCoV testing.
- Assess effectiveness of environmental cleaning procedures (<https://www.cdc.gov/HAI/toolkits/Evaluating-Environmental-Cleaning.html>); provide education/refresher training for environmental services personnel.
- Review policies and procedures for monitoring and managing HCP with potential for exposure to 2019-nCoV, including ensuring that HCP have ready access, including via telephone, to medical consultation.
- Ensure that appropriate HCP have been medically cleared, fit-tested, and trained for respirator use.
- Provide education and refresher training to HCP regarding 2019-nCoV diagnosis, how to obtain specimen testing, appropriate PPE use, triage procedures including patient

placement, HCP sick leave policies, and how and to whom 2019-nCoV cases should be reported, procedures to take following unprotected exposures (i.e., not wearing recommended PPE) to suspected 2019-nCoV patients at the facility.

- Review plans for visitor access and movement within the facility
- Ensure that specific persons have been designated within the facility who are responsible for communication with public health officials and dissemination of information to other HCP at the facility.
- Confirm the local or state health department contact for reporting 2019-nCoV cases and confirm reporting requirements.
- Monitor the situation on CDC's web page 2019 Novel Coronavirus, Wuhan, China (<https://www.cdc.gov/coronavirus/2019-ncov/index.html>)

This information is also available online at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/hcp-hospital-checklist.html>

Healthcare Personnel Preparedness Checklist for 2019-nCoV

Front-line healthcare personnel in the United States should be prepared to evaluate patients for 2019 novel coronavirus (2019-nCoV). The following checklist highlights key steps for healthcare personnel in preparation for transport and arrival of patients potentially infected with 2019-nCoV.

- ☐ Stay up to date on the latest information about signs and symptoms, diagnostic testing, and case definitions for 2019-nCoV disease (<https://www.cdc.gov/coronavirus/2019-nCoV/summary.html>).
- ☐ Review your infection prevention and control policies and CDC infection control recommendations for 2019-nCoV(<https://www.cdc.gov/coronavirus/2019-nCoV/infection-control.html>) for:
 - ☐ Assessment and triage of patients with acute respiratory symptoms
 - ☐ Patient placement
 - ☐ Implementation of Standard, Contact, and Airborne Precautions, including the use of eye protection
 - ☐ Visitor management and exclusion
 - ☐ Source control measures for patients (e.g., put facemask on suspect patients)
 - ☐ Requirements for performing aerosol generating procedures
- ☐ Be alert for patients who meet the persons under investigation (PUI)(<https://www.cdc.gov/coronavirus/2019-nCoV/infection-control.html>) definition
- ☐ Know how to report a potential 2019-nCoV case or exposure to facility infection control leads and public health officials
- ☐ Know who, when, and how to seek evaluation by occupational health following an unprotected exposure (i.e., not wearing recommended PPE) to a suspected or confirmed nCoV patient
- ☐ Remain at home, and notify occupational health services, if you are ill
- ☐ Know how to contact and receive information from your state or local public health agency

This information is also available online at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/hcp-personnel-checklist.html>

GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING VIRAL PATHOGENS NOT ON EPA-REGISTERED DISINFECTANT LABELS

August 19, 2016

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I. Background and Purpose

Emerging pathogens are an increasing public health concern in the United States as well as globally. Many of the emerging pathogens of greatest concern are pathogenic viruses, and the ability of some of these viruses to persist on environmental surfaces can play a role in human disease transmission. Because the occurrence of emerging viral pathogens is less common and predictable than established pathogens, few, if any, EPA-registered disinfectant product labels specify use against this category of infectious agents. Also, the pathogens are often unavailable commercially and standard methods for laboratory testing may not have been developed. Thus, it can be difficult to assess the efficacy of EPA-registered disinfectants against such pathogens in a timely manner and to add these viruses to existing product registrations, which requires the submission of efficacy data for agency review. As a result, the agency is providing a voluntary, two-stage process to enable use of certain EPA-registered disinfectant products against emerging viral pathogens not identified on the product label.

1) In the first stage, which may be performed prior to any outbreak, registrants with an eligible disinfectant product may submit a request, via label amendment or during the registration of a new product, to control a specific emerging viral pathogen to add a designated statement (see Attachment 1) to the master label and additional terms to the product registration. If the product meets the eligibility criteria suggested in this Guidance, the agency generally will approve the amendment. Approval of the amendment would include additional terms and conditions of registration regarding how the designated statement may be published and communicated.

2) The second stage of this process occurs during a human or animal disease outbreak caused by an emerging virus. In this stage, registrants of products with the previously mentioned label amendment and terms of registration would be allowed to use the designated statement in off-label communications intended to inform the user community/public that the disinfectant product(s) may be used against the specific emerging viral pathogen. These off-label statements can inform the public about the utility

of these products against the emerging pathogen in the most expeditious manner and can be more easily removed once the outbreak has ended than statements on a label.

Note that this document provides general guidance to EPA, pesticide registrants, applicants for pesticide registrations, and the public. This guidance is not binding on EPA or any outside parties, and EPA may depart from the guidance where circumstances warrant and without prior notice.

II. Viral Subgroup Classification

EPA and the Centers for Disease Control and Prevention (CDC) recognize that certain microorganisms can be ranked with respect to their tolerance to chemical disinfectants. The Spaulding Classification model, used by CDC, tiers microorganisms in accordance with the level of resistance to being killed (inactivation) by typical disinfectant products.¹ With this approach viruses are divided into three viral subgroups (small non-enveloped, large non-enveloped, and enveloped) based on their relative resistance to inactivation (see below). According to this hierarchy, if an antimicrobial product can kill a small, non-enveloped virus it should be able to kill any large, non-enveloped virus or any enveloped virus. Similarly, a product that can kill a large, non-enveloped virus should be able to kill any enveloped virus.

Small, Non-Enveloped Viruses (<50 nm): These small, non-enveloped viruses can be highly resistant to inactivation by disinfection. Despite the lack of a lipid envelope, these organisms have a very resistant protein capsid. The following are viral families in the small non-enveloped subgroup: (1) Picornaviridae, (2) Parvoviridae, (3) Caliciviridae, (4) Astroviridae, and (5) Polyomaviridae.

Large, Non-Enveloped Viruses: Compared to small, non-enveloped viruses, these viruses are less resistant to inactivation by disinfection. Although they have a resistant protein capsid, their larger size (50-100nm) makes them more vulnerable than their smaller viral counterparts. The following are viral families in the large non-enveloped subgroup: (1) Adenoviridae, (2) Reoviridae, and (3) Papillomaviridae.

Enveloped Viruses: Enveloped viruses are the least resistant to inactivation by disinfection. The structure of these viruses includes a lipid envelope, which is easily compromised by most disinfectants. Once the lipid envelope is damaged, the integrity of the virus is compromised, thereby neutralizing its infectivity. The following are viral families in the enveloped subgroup: (1) Arenaviridae, (2) Bornaviridae, (3) Bunyaviridae, (4) Coronaviridae, (5) Filoviridae, (6) Flaviviridae, (7) Hepadnaviridae, (8) Herpesviridae, (9) Orthomyxoviridae, (10) Paramyxoviridae, (11) Poxviridae, (12) Retroviridae, (13) Rhabdoviridae, and (14) Togaviridae.

Under the criteria outlined in Section III of this Guidance, this hierarchy is used to determine a product's anticipated efficacy against an emerging viral pathogen.

III. Product Eligibility Criteria

Registrants should use the following criteria to determine if an EPA-registered disinfectant product is eligible to use the process described in this Guidance. An eligible product should meet both of the following criteria:

1. The product is an EPA-registered, hospital/healthcare or broad-spectrum disinfectant with directions for use on hard, porous or non-porous surfaces².
2. The currently accepted product label (from an EPA registered product as described above in III.1) should have disinfectant efficacy claims against at least one of the following viral pathogen groupings:
 - a) A product should be approved by EPA to inactivate at least one large or one small non-enveloped virus **to be eligible for use against an enveloped emerging viral pathogen.**
 - b) A product should be approved by EPA to inactivate at least one small, non-enveloped virus **to be eligible for use against a large, non-enveloped emerging viral pathogen.**
 - c) A product should be approved by EPA to inactivate at least two small, non-enveloped viruses with each from a different viral family **to be eligible for use against a small, non-enveloped emerging viral pathogen.**

This approach, where disinfectant products registered for use against viral pathogens in one category of the Spaulding Classification model can be presumed effective against viral pathogens in less-resistant categories, is intended to serve as a conservative approach to identifying disinfectant products likely to be effective against emerging pathogens. However, since there is no viral subgroup known to be more resistant than small, non-enveloped viral pathogens, a disinfectant product must be proven to be efficacious against at least two small, non-enveloped viral pathogens from different viral families in order to be eligible for emerging pathogen claims pursuant to this guidance in regard to an outbreak of an emerging small, non-enveloped viral pathogen.

IV. Instructions for Using the Process

The following are instructions for registrants (with a product eligible under Section III above) who wish to use the process in this document for making claims against emerging viral pathogens. Registrants are encouraged to submit either an FQPA (fast-track, non-PRIA) or a PRIA label amendment request explaining why the product meets the criteria for use against one or more categories of emerging [**enveloped / large non-enveloped / small non-enveloped**] viral pathogens as suggested in this guidance.

This application may be submitted at any time, including during the new product registration process, and should include a request to add to the Terms of Registration for the product a product-specific version of the language in Attachment 1, and include each of the conditions governing the use of such statements that appear in Attachment 1. If approved, the registrant will be authorized to make the product-specific version of the statement(s) described in Attachment 1 in the event of an applicable disease outbreak as

provided in this Guidance. The conditions stated in Attachment 1, which would be incorporated into the terms of registration, identify the allowable statements, the outlets through which the use statements may be communicated, and the time periods during which the use statements may be made. Use of the designated statements in circumstances other than those specified in the terms of registration would be a violation of FIFRA section 12(a)(1)(B), unless otherwise authorized by EPA.

V. Outbreak Criteria Associated with Emerging Pathogens Process

As stated above, the process described in this Guidance is for use with emerging pathogens associated with certain human or animal disease outbreaks. Thus, registrants whose registered master labels include the approved statements, either via label amendment or during the new registration process as described in Section IV above, may publish the approved statements only upon a disease outbreak that meets all the following criteria:

1. The causative organism should be a virus that causes an infectious disease that has appeared in a human or animal population for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range ("emerging viral pathogen").³ It includes both new and re-emerging viral pathogens listed by either the CDC or the World Organization for Animal Health (OIE) in one of the publications below.
 - a. For human disease, the outbreak is listed in one of the following CDC publications:
 - i. CDC Current Outbreak List for "U.S. Based Outbreaks" (www.cdc.gov/outbreaks),
 - ii. CDC Current Outbreak List for "Outbreaks Affecting International Travelers" with an "Alert" or "Advisory" classification (www.cdc.gov/outbreaks) (also released through the CDC's Health Alert Network (HAN) notification process)
 - iii. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - b. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the United States of America on the OIE Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
2. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup (small non-enveloped, large non-enveloped, enveloped) should be determined. See OIE technical disease cards ().
3. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.

An example of how both the application and outbreak process might work is presented in Attachment 2.

VI. References

¹ Spaulding E.H. 1968. Chemical disinfection of medical and surgical materials. Disinfection, Sterilization, & Preservation, 3rd Edition, Block S (Ed), (Lea & Febiger, Philadelphia, PA).

² [Product Performance Test Guidelines: OCSPP 810.2200 Disinfectants for Use on Hard Surfaces – Efficacy Data Recommendations \[EPA 712-C-07-074\]](#)

³ World Health Organization (WHO). 2015. Emerging Diseases. Available from: http://www.who.int/topics/emerging_diseases/en/

Attachment 1

Example Terms of Registration Associated with the Guidance for Making Claims against Emerging Viral Pathogens Not on EPA-Registered Disinfectant Labels

The following are examples of additional Terms of Registration that EPA anticipates resulting from a request to amend a registration for the reasons addressed in EPA's 2016 Guidance to Registrants: Process for Making Claims against Emerging Viral Pathogens Not on EPA-Registered Disinfectant Labels:

1. The statements shall be made only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

2. Statements shall adhere to one or both of the following formats:

[Product name] has demonstrated effectiveness against viruses similar to **[name of emerging virus]** on hard, **[porous and/or non-porous surfaces]**. Therefore, **[product name]** can be used against **[name of emerging virus]** when used in accordance with the directions for use against **[name of supporting virus(es)]** on **[hard, porous/non-porous surfaces]**. Refer to the **[CDC or OIE]** website at **[pathogen-specific website address]** for additional information.

[Name of illness/outbreak] is caused by **[name of emerging virus]**. **[Product name]** kills similar viruses and therefore can be used against **[name of emerging virus]** when used in accordance with the directions for use against **[name of supporting virus(es)]** on **[hard, porous/non-porous surfaces]**. Refer to the **[CDC or OIE]** website at **[website address]** for additional information.

3. The registrant may begin communicating these statement(s) upon notification on the CDC or OIE website identified under Section V of the Guidance of an outbreak of an emerging **[small non-enveloped, large non-enveloped, and/or enveloped]** viral pathogen. The registrant shall cease and remove all such non-label communications intended for consumers no later than 24 months after the original notification of the outbreak on the CDC or OIE website, unless the agency provides guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

4. The registrant agrees that paragraphs 1 through 3 above shall become immediately void and ineffective if registration for use against **[name of supporting virus(es)]** is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category would also be grounds for voiding paragraphs 1 through 3.

Attachment 2

Example of the Process

The following is a hypothetical scenario for how registrants and EPA could use the process identified in this Guidance, using an Enterovirus D68 outbreak as an example.

Before an outbreak occurs:

- Prior to the occurrence of an outbreak, registrants interested in using this process apply for registration amendments as suggested in this Guidance to allow claims of anticipated efficacy against small non-enveloped viruses. Once EPA has approved the amendments, the subject products' registrations will indicate that certain claims specified in the registration may be made regarding use against emerging small non-enveloped viral pathogens, subject to the products' Terms of Registration as described in Attachment 1. For example, a registrant whose product is registered for use against two small non-enveloped viral pathogens might request the following product-specific statement:

Product Z has demonstrated effectiveness against viruses similar to **[name of emerging virus]** on hard non-porous surfaces. Therefore this product can be used against **[name of emerging virus]** when used in accordance with the directions for use against Virus X and Virus Y on hard, non-porous surfaces. Refer to the **[CDC or OEI]** website at **[website address]** for additional information.

- EPA would review the claims and, if approved, add this statement to the product's master label as a non-label claim permitted only when certain emerging viral pathogen conditions are met.

After an outbreak occurs:

- In the event of an Enterovirus D68 public health outbreak, the Centers for Disease Control and Prevention would communicate the outbreak threat via its website (www.cdc.gov/outbreaks), identify the viral pathogen taxonomy, and indicate that surface disinfection is recommended.

1. With the viral pathogen information provided by CDC, registrants would determine that the pathogen, Enterovirus D68 (a member of the Picornaviridae family), is a small non-enveloped virus.

2. At this point, registrants with products whose registrations have been amended to allow certain claims of anticipated efficacy against two or more small non-enveloped viral pathogens from different viral families would be allowed to make those claims specified in the terms of registration as illustrated in Attachment 1 regarding use of the products against Enterovirus D68 without further submissions to, or review by, EPA. For example, a registrant whose registration was previously amended to include the product-specific language in the example above would now be allowed to include the following statement in technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, non-label related websites, consumer information services, and social media sites:

Product Z has demonstrated effectiveness against viruses similar to Enterovirus D68 on hard non-porous surfaces. Therefore, this product can be used against Enterovirus D68 when used in accordance with the directions for use against Virus X and Virus Y on hard, non-porous surfaces. Refer to the CDC website at www.cdc.gov/... for additional information.